

### **REMARKS**

Claims 4, 5 and 8-12 remain in the application for further prosecution. By this amendment, claims 10-12 have been amended. New claims 13-16 have been added.

### **Claim Rejections - 35 U.S.C. § 103**

Claims 4, 5, 8-10 and 12 are rejected under 35 U.S.C. 103 as obvious over McEwan (U.S. Patent No. 4,828,716) in view of Kelly (U.S. Patent No. 6,074,883).

The present claims relate to a method of collecting, separating and recovering a platelet-rich concentrate from a patient's blood. The method in claim 4 includes collecting a patient's blood in an elongated container. The blood is centrifuged in the container to separate the blood into platelet-rich plasma and red blood cells. The red blood cells are expelled from the container through tubing into a waste bag via a plunger. The platelet-rich plasma remaining in the container is centrifuged to separate a platelet-rich concentrate from a platelet-poor plasma. A hollow plunger rod having a port is attached to the plunger and the platelet-poor plasma is expelled to a waste bag. The platelet-rich concentrate remaining in the container is then recovered. Claim 5 differs from claim 4 in that claim 5 includes centrifuging the blood in a single step to separate the blood into platelet-poor plasma, red blood cells, and platelet-rich concentrate. Neither McEwan nor Kelly alone or in combination discloses all of the elements of claims 4 and 5.

McEwan is directed toward a system to collect blood samples and separate the blood into a lighter non-cellular component (serum or plasma) and a denser cellular component (e.g., red blood cells). (Col.12, ll. 1-4). An optical detector 94 is used to determine the separation between the non-cellular and cellular components. (Col. 11, ll. 25-36). The serum or plasma is collected to a serum collection chamber 74. (Col. 11, ll. 48-53). McEwan does not disclose obtaining platelet concentrate from platelet rich plasma. Further, the Office Action concedes

that McEwan does not disclose expelling the separated red blood cells into a waste bag, attaching a hollow plunger rod to displace the separated platelet poor plasma, a soft and heavy spin, or the collection container containing a small amount of anti-coagulant. (page 4).

The Examiner has also cited Kelly which discloses a carrier system to assist in the holding of a blood carrier tube in a centrifuge. Kelly does not teach nor suggest separating plasma from blood cells, nor separating platelet concentrate from platelet rich plasma. Contrary to the assertion that Kelly discloses a plunger with a hollow plunger rod for removing separated components, the elements cited by page 4 of the Office Action do not perform this function. The operation of the carrier tube 100 described with reference to Figures 16-21 (Col. 8, l. 36-Col. 9, l. 66) only disclose moving the cap 104 of the carrier tube 102 into the capillary tube 114 to create a seal to prevent blood or air to flow out. (Col. 9, ll. 55-66). Nowhere in this section, nor anywhere else in Kelly is there any teaching of using the carrier tube 102 (asserted to be a plunger) to remove separated components of the blood from the capillary tube 114. In fact, Kelly only discloses analysis of separated components, all of which remain in the capillary tube 114 after centrifuge, via an optical reading device. (Col. 6, ll. 10-15; Col. 10, ll. 32-43).

There is no suggestion or motivation to combine McEwan and Kelly. In fact Kelly would suggest away from such a combination because Kelly relies on optical sensing of the separated components in one container while McEwan discloses separating serum from cellular components of blood for subsequent analysis of the serum alone. One of ordinary skill in the art would not look to a technique which retains all the separated components in a container such as Kelly to solve problems raised by a technique which removes different components from the container such as McEwan.

Even if such a combination were made, the combination does not disclose nor suggest all the elements of claims 4 and 5. Specifically, neither McEwan nor Kelly disclose centrifuging to

separate platelet poor plasma from platelet concentrate as required by claims 4 and 5. The Office Action has cited McEwan on Col. 14, ll. 43-51 that components may be further separated. However, this section only refers to separation of the “lower density component” from the “denser cellular component.” (Col. 14, ll. 46-49). The lighter, low density, non-cellular component is defined by McEwan as serum or plasma while the denser cellular component contains blood cells. (Col. 11, ll. 25-30). Thus, the separation of McEwan does not relate to the separation of platelet concentrate from plasma or serum as in the pending claims. The combination of Kelly and McEwan thus would only separate the blood into serum and cellular material and therefore not anticipate the separation of platelet concentrate from the serum or plasma as in claims 4 and 5.

Further, the combination of McEwan and Kelly does not anticipate “attaching a hollow plunger rod to displace the separated platelet poor plasma” or moving a plunger to expel the red blood cells as required by claims 4 and 5. The Office Action has cited Kelly for disclosing a plunger 102 which has a hollow plunger rod 118 for removing separated components. (page 4). However as explained above, Kelly only discloses use of the plunger to seal the blood in the centrifuge container. Kelly does not suggest nor disclose using the plunger 102 to remove separated components let alone separated platelet poor plasma after the centrifuge process as required by claims 4 and 5. Thus, the combination of Kelly and McEwan would not disclose use of a plunger to expel either the separated red blood cells or the platelet poor plasma as required by claims 4 and 5. For at least these reasons, claims 4 and 5 are allowable over Kelly and McEwan. Claims 8-10 and 12 depend from claim 4 and are also allowable.

Applicant has also added new claim 16. New claim 16 is also allowable over Kelly and McEwan for the same reasons that claims 4 and 5 are allowable, namely that the combination of Kelly and McEwan does not disclose nor suggest “separating a platelet-rich concentrate from a

platelet poor plasma” or attaching a hollow plunger rod to displace “the platelet-poor plasma from said container.”

**Other amendments**

The Examiner has indicated that claim 11 is allowable if rewritten in independent form. Applicant has amended claim 11 to incorporate the limitations of the base claim and respectfully submits that amended claim 11 is now patentable.

Applicant has amended claims 10 and 12 to eliminate the multiple dependency of such claims and added new claims 13-15 to incorporate the same subject matter of claims 11-12 with reference to claim 5.

As recommended by the Examiner, Applicant has amended the specification to reference the patent number of the now issued parent application.

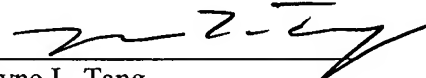
**Conclusion**

It is Applicant's belief that all of the pending claims (1-16) are now in condition for allowance and actions towards that effect is respectfully requested.

If there are any matters which may be resolved or clarified through a telephone interview, the Examiner is respectfully requested to contact the undersigned attorney at the number indicated.

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Respectfully submitted,

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